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Low Clinical Event Rates In Real-World Patients with Acute Myocardial Infarction Receiving XIENCE V® Everolimus-Eluting Stents: One-Year Results From the XIENCE V USA Study

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Background: The XIENCE V® Everolimus-eluting Coronary Stent (XIENCE V; Abbott Vascular) was superior to TAXUS® (Boston Scientific) in angiographic and clinical outcomes in the SPIRIT II, III, and IV randomized controlled trials. However, these earlier trials excluded patients with acute myocardial infarction (AMI) as the admitting diagnosis. As little information exists on the performance of XIENCE V in real-world AMI patients, the objective of this analysis was to evaluate the safety and efficacy of XIENCE V in patients with AMI.
Methods: XIENCE V USA is a large, prospective, multicenter, unrestricted, real-world study required by the US FDA as post-market surveillance. Consecutive patients undergoing PCI with XIENCE V were enrolled between July and December 2008. In this analysis, clinical outcomes in patients with (n=761) and without AMI (n=3455) were compared at 1 year. AMI (both STEMI and non-STEMI combined) was diagnosed based on clinical assessment including ECG and/or cardiac enzymes. Clinical outcomes were adjudicated by an independent Clinical Event Committee.
Results: Mean age, gender distribution, lesion length, number of lesions and vessels treated, number of implanted stents, maximum balloon pressures, and device successes were similar across the two groups. The AMI group had fewer diabetics compared to the non-AMI group (29.4% vs. 37.0%, p<0.0001). At 1 year, 77.1% of patients in the AMI group remained on dual antiplatelet therapy vs. 80.3% in the non-AMI group, p=0.055. Overall ARC-defined definite and probable stent thrombosis (ST) rates were 1.1% in the AMI group vs. 0.9% in the non-AMI group (p=0.522). The late ST (30 days-1 year) rates were 0.3% vs. 0.5% (AMI vs. non-AMI), p=0.757. Rates of clinically indicated (CI) TLR were 3.9% vs. 4.4% (AMI vs. non-AMI), p=0.618, and rates of target lesion failure (TLF: composite of cardiac death, ARC-defined MI attributed to target vessel, and CI-TLR) were 9.1% vs. 8.5%, (AMI vs. non-AMI), p=0.564.
Conclusion: In this multicenter, real-world, large US study, AMI patients treated with XIENCE V had low rates of ST, CI-TLR, and TLF that were similar to non-AMI patients at 1 year. These results demonstrate the safety and efficacy of XIENCE V in this high-risk patient population. Improvement in quality of life outcomes in this subgroup will also be presented.

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Improved Periprocedural Side Branch Flow with TAXUS Liberté in Long Lesions: A Comparative Analysis with Multiple Stents in TAXUS V

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Background: In the TAXUS V trial, the rate of periprocedural myocardial infarction (MI) with implantation of multiple TAXUS Express (TE) stents in long lesions (LL) was increased compared to multiple bare metal Express stents (BMS) due to greater side branch compromise. This may not be the case with the thinner strut TAXUS Liberté (TL); in TAXUS ATLAS LL, the 38 mm TL stent lowered the periprocedural MI rate compared with the TE. This analysis compares side branch angiographic profiles for patients receiving the TL stent in TAXUS ATLAS LL with patients receiving multiple stents in TAXUS V.
Methods: A *post hoc* core laboratory analysis of angiographic results from all TL patients in TAXUS ATLAS LL and blinded analysis of all multiple stented patients in TAXUS V. Side branches with RVD >1 mm were included in the analysis, and up to 3 side branches per lesion were analyzed.
Results: Reduced side branch TIMI flow during the procedure correlated with the rate of periprocedural MI, mostly non-Q-wave (Table). Reduced side branch TIMI flow at any point during the procedure occurred less often in patients treated with TL (11.3%) than BMS (19.0%; p=0.01) or TE (29.1%; p<0.001). Whereas side branch TIMI flow reduction was transient with multiple BMS implantation, side branch blood flow reduction was more commonly sustained with multiple TE than TL (22.1% vs 8.7%, p<0.001).

Clinical and Angiographic Results					
	TAXUS Liberté 38 mm (N=150 patients/ N=329 side branches)	BMS Express multiple stents (N=184 patients/ N=268 side branches)	p value (TL vs BMS)	TAXUS Express multiple stents (N=188 patients/ N=289 side branches)	p value (TL vs TE)
Baseline features (QCA)					
Lesion length (mm)	28.08 ± 8.31	25.69 ± 10.40	0.02	24.88 ± 9.48	0.002
RVD (mm)	2.80 ± 0.42	2.68 ± 0.56	0.03	2.66 ± 0.55	0.02
Thrombus (%)	0.7	4.3	0.045*	7.4	0.003
Type C lesions (AHA/ACC criteria, %)	83.3	75.0	0.06	72.3	0.02
Side branch diameter, mm	1.46 ± 0.32	1.40 ± 0.36	0.04	1.42 ± 0.37	0.22
..Branch vessel disease (%)	13.3	13.2	0.97	8.5	0.15
..Side branch stenosis (%)	68.50 ± 13.68	69.33 ± 13.57	0.84	68.63 ± 12.98	0.98
Side branch analysis (QCA)					
Side branch reduced TIMI** flow, %					
Any time point	11.3	19.0	0.01	29.1	<0.001
Baseline	0.3	1.5	0.19*	2.5	0.03*
After predilation	1.0	3.8	0.02	6.3	<0.001
After first stent	9.4	10.3	0.71	15.1	0.03
After additional stents	17.0	12.9	0.45	20.7	0.56
End of procedure	8.7	12.9	0.10	22.1	<0.001
Location of reduced flow, %					
..Outside stent segment	0.0	27.3	0.005*	0.0	Undefined
..Within segment (non-overlap)	14.7	25.1	0.005	32.9	<0.001
..Within overlap region	0.0	25.0	>0.99*	47.3	>0.99*
30-Day Clinical outcomes					
MI	0.0	3.3	0.03*	8.6	<0.001
..Q-Wave MI	0.0	0.0	Undefined	1.1	0.50*
..Non-Q-Wave MI	0.0	3.3	0.03*	7.5	<0.001

Numbers shown are % (count/total) or mean ± SD (n).
Default p value for comparing two proportions is from the chi-square test.
*p values were calculated by Fisher exact test.
**Thrombolysis in Myocardial Infarction flow
Abbreviations: BMS=bare-metal stent; TL=TAXUS Liberté; TE=TAXUS Express; QCA=quantitative coronary angiography RVD=reference vessel diameter; AHA=American Heart Association; ACC=American College of Cardiology; MI=myocardial infarction.

Conclusions: The present analysis suggests that treating long lesions with a 38 mm TL rather than either multiple TE or BMS less frequently impairs blood flow in side branches, resulting in a reduced 30 day rate of MI. Preservation of side branch TIMI flow and MI reduction with TL in the single stent strut regions demonstrates the importance of stent design and thinner strut stents for long lesions.

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Does Xience V Stent Reduce the Clinical Outcome Gap Between Diabetic and Non-Diabetic Patients? A Long-Term Single-Center Analysis

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Background: Spirit IV trial showed significantly better safety and efficacy of Xience V (XV; Abbott Vascular, Illinois, USA) compared to Taxus (Boston Scientific, Natick, MA, USA) stent. This outcome difference was not present in diabetic (D) patients.
Aim of the study: To compare the clinical outcomes in real-world D and non-diabetic (ND) patients treated with XV.
Methods: Between November 2006 and December 2008, 1319 patients (81% male, mean age 65±9 years) undergoing XV implantation were enrolled and followed for up to 3 years. D (n=168, 12.7%) patients were compared to ND (n=1151) patients.
Results. D pts were more hypertensive (72.6% vs. 45.5%, p<0.001) and more often had stable angina (82% vs 71%, p=0.004). Coronary stenting in D was performed more frequently for 2/3 vessel disease (69.6% vs 47.2%, p< 0.001), long lesions (> 30 mm: 53% vs 54%, p=0.92) and small vessels (≤ 2.5 mm: 38% D vs 27% ND, p=0.005). Mean stented segment length per patient and per lesion was similar in both groups. Two early stent thrombosis occurred in ND (0.17%) group. Cumulative in-hospital MACE was 12% in D vs 5.8% in ND (p=0.065), mainly due to post-procedural non-Q MI (> x 3 CK-MB) (8.9% in D vs 5.3% in ND, p=0.067). Six-month TLR and cumulative MACE were very low and comparable in both groups. These positive results were maintained on long-term (mean 27.7±13 months) follow-up (Table). One late stent thrombosis was observed in ND while no very late stent thrombosis occurred at all.

Six- and twenty-four month follow-up

	Six.Month F/U		p-value	24-Month F/U		p-value
	D (168 patients)	ND (1151 patients)		D (133 patients)	ND (960 patients)	
Death, any	1 (0.7%)	0	0.009	3 (2.2%)	8 (0.8%)	0.12
- Cardiac death	0	0	1.0	2 (1.5%)	2 (0.2%)	0.02
MI	1 (0.7%)	3 (0.3%)	0.43	1 (0.7%)	1 (0.1%)	0.10
RePCI	12 (9%)	78 (8.1%)	0.75	7 (5.2%)	35 (3.6%)	0.36
TLR/TVR	4 (3%)	14 (1.4%)	0.18	4 (3%)	6 (0.6%)	0.007
CABG	0	0	1.0	0	0	1.0
MACE	14 (10.5%)	81 (8.4%)	0.42	11 (8.2%)	44 (4.5%)	0.06

Conclusions: Treatment of real-world coronary lesions with XV is safe and associated with similar and excellent immediate and six-month clinical outcomes in D and ND. At 24 months, D showed a moderate but significantly higher rate of TLR/TVR compared to ND.

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The Sirolimus-eluting Cypher Select® Plus Coronary Stent For The Treatment Of Previous Bare-metal And Drug-eluting Stent Restenosis: An Insight From The E-select Registry

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Aim: To determine the one-year efficacy and safety of Sirolimus-eluting CYPHER Select® or CYPHER Select® Plus stents (SES) for the treatment of previous bare-metal (BMS) and drug-eluting stent (DES) restenosis (ISR) in complex, non-selected, real-world patients from the e-SELECT registry.
Methods and results: The e-SELECT registry is a web-based, multicentric and multinational (320 hospitals in 56 countries) registry encompassing virtually all subsets of patients and lesions treated

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